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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,500	03/24/2004	Eberhard Weihe	029310.53352US	4381

23911 7590 04/21/2006

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,500	WEIHE ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 65 are pending in the instant application.

2) Claims 1 to 65 are objected to as reciting an improper Markush Group.

M.P.E.P. 803.02 states that:

> "Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

The seven different amino acid sequences recited in claim 1, for example, do not share a common utility that is based upon a common structural feature or combination of features that distinguishes them as group from the prior art. Further, a transporter protein, a nucleic acid encoding that protein, a polynucleotide that is antisense thereto, a ligand to that transporter protein (glutamic acid), and an antibody thereto are five structurally unrelated classes of compounds that are not distinguished as a group from the prior art, irrespective of any functional relationship they may have relative to some common reference molecule.

Correction is required.

3) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I to VII. Claims 1 to 17, 49, 54, 55 and 57 to 62, only in so far as they relate to an assay employing a **polypeptide** comprising **one** of the seven

different amino acid sequences recited therein, classified in class 436, subclass 501. Invention I includes claims 1 to 17, 49, 54, 55 and 57 to 62 only in so far as they relate to a polypeptide comprising SEQ ID NO:2 whereas invention VII includes these claims only in so far as they relate to a polypeptide comprising SEQ ID NO:14.

VIII to XIV. Claims 18 and 19, only in so far as they relate to a compound of unspecified constitution that binds to a polypeptide comprising one of the seven different amino acid sequences recited therein, classification undeterminable.

XV to XXI. Claims 20, 21, 23, 24, 28, 30 to 40, 42, 43, 47 and 63 to 65, only in so far as they relate to a method of treating or diagnosing by **administering a polynucleotide encoding** a polypeptide comprising **one** of the seven different amino acid sequences recited therein, classified in class 514, subclass 44.

XXII to XXVIII. Claims 20, 22 to 24, 28, 30 to 43, 47 and 63 to 65, only in so far as they relate to a method of treating or diagnosing by administering a polynucleotide that is **antisense** to a polynucleotide encoding a polypeptide comprising **one** of the seven different amino acid sequences recited therein, classified in class 514, subclass 44.

XXIX to XXXV. Claims 20, 21, 23, 25, 26, 28, 39, 42 to 45, 47 and 63 to 65, only in so far as they relate to a method of treating or diagnosing by

administering a polypeptide comprising **one** of the seven different amino acid sequences recited therein, classified in class 514, subclass 2

XXXVI to XLII. Claims 20, 21, 23, 27, 28, 39, 42, 43, 46, 47 and 63 to 65, only in so far as they relate to a method of treating or diagnosing by **administering an antibody** that binds to a polypeptide comprising **one** of the seven different amino acid sequences recited therein, classified in class 424, subclass 143.1.

XLIII to XLIX. Claims 20, 21, 23, 29, 39, 42, 43, 48 and 63 to 65, only in so far as they relate to a method of treating or diagnosing by **administering a compound** of unspecified constitution that binds to a polynucleotide encoding a polypeptide comprising **one** of the seven different amino acid sequences recited therein, classification undeterminable.

L to LVI. Claims 49, 50, 52, 53 and 57 to 61, only in so far as they relate to an assay employing **a polynucleotide encoding** a polypeptide comprising **one** of the seven different amino acid sequences recited therein, classified in class 435, subclass 7.21.

LVII to LXIII. Claims 49, 51, 52, 53 and 57 to 61, only in so far as they relate to an assay polynucleotide that is **antisense** to a polynucleotide encoding a polypeptide comprising **one** of the seven different amino acid sequences recited therein, classified in class 435, subclass 6.

LXIV to LXX. Claims 49, 52 53 and 56 to 61, only in so far as they relate to an assay employing **an antibody** that binds to a polypeptide comprising **one**

of the seven different amino acid sequences recited therein, classified in class 436, subclass 536.

The inventions are distinct, each from the other because of the following reasons:

Inventions I to VII and XV to LXX are two materially different methods of using up to thirty five materially different compounds, The seven different proteins, seven different polynucleotides, seven different rybozymes, seven different antibodies and seven different binding compounds recited, for example, in claim 20, do not reflect a common inventive concept because each of these thirty five different compounds can be made and used without the others and because they lack a common structural feature or combination of features that distinguishes them as a group from the prior art. Further, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, a binding assay that employs an antibody has a different mode of operation from one that employs a receptor protein, whose mode of operation is also different from an assay that employs an antisense polynucleotide, etc. This is also true for a method of treating that employs a peptide relative to a method that employs an antibody or a polynucleotide. Therefore, a search of the art for a binding assay employing any one of the thirty five different compounds recited in claim 20 would not be coextensive with a search for an assay employing any one or more of the others. In addition, a search of the art for a binding assay employing, for example, a glutamate transporter protein, which is the subject of inventions I to VII, would not encompass any of the art relating to methods of treating by

administering a glutamate analog, as recited in inventions XLIII to XLIX. Therefore, a search of any two or more of the claimed inventions in a single application clearly constitutes an undue burden.

The binding compounds of inventions VIII to XIV are each related to the methods of treating that are inventions XLIII to XLIX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the compound, as claimed, can be used in a materially different process such as in an assay to identify antagonists thereto.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4) Claims 1 to 65 are generic to the following disclosed patentably distinct species of diseases and disorders as listed in claim 1. The species are independent or distinct because they have different causes, different symptoms and different pathologies. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1600